REMARKS

The Specification has been amended to correct various informalities. Claims 73, 75, 77, 78, 80, 81, 83, 91-92, 215, 217, 218, and 231-233 have been amended. Claims 93, 238, and 239 have been canceled. Claims 1-72, 74, 76, 94-214, and 216 were previously canceled. New Claim 240 has been added. No new matter has been added thereby. Claims 73, 75, 77-92, 215, 217-237, and 240 are currently pending, of which Claims 89-90, 220-230, and 234-237 were previously withdrawn from consideration as directed to non-elected species. Thus Claims 73, 75, 77-88, 91, 92, 215, 217-219, 231-233, and 240 are currently under consideration. Applicants respectfully request consideration of the amendments and remarks below.

Specification

The Brief Description of the Drawings section of the Specification has been amended to include descriptions of Figures 22A-22H and to correct certain typographical errors.

Support for new Paragraph [0055] can be found, for example, in the Specification in Paragraphs [0150] and [0151].

New Paragraph [0055A] explains that "FIG. 22A is a graph showing *in vitro* induction of mRNA in whole blood." Support for this amendment can be found, for example, in the Specification in Paragraph [0151].

New Paragraph [0055B] explains that "FIG. 22B is a graph showing blood storage before *in vitro* stimulation." Support for this amendment can be found, for example, in the Specification in Paragraph [0151].

New Paragraph [0055C] explains that "FIG. 22C is a graph showing *in vitro* induction of FasL mRNA among various subjects, by showing mRNA molecules/mL blood for both stimulation and vehicle control, respectively." Support for this amendment can be found, for example, in the Specification in Paragraph [0152], Paragraph [0150], and FIG. 22C itself. Paragraph [0150] explains that the ◆ symbol represents FasL.

New Paragraph [0055D] explains that "FIG. 22D is a graph showing *in vitro* induction of p21 mRNA among various subjects, by showing mRNA molecules/mL blood for both stimulation and vehicle control, respectively." Support for this amendment can be found, for example, in the

Specification in Paragraph [0152], Paragraph [0150], and FIG. 22D itself. Paragraph [0150] explains that the ▲ symbol represents p21.

New Paragraph [0055E] explains that "FIG. 22E is the same graph as FIG. 22C rotated until the regression line becomes horizontal." Support for this amendment can be found, for example, in the Specification in Paragraph [0152].

New Paragraph [0055F] explains that "FIG. 22F is the same graph as FIG. 22D rotated until the regression line becomes horizontal." Support for this amendment can be found, for example, in the Specification in Paragraph [0152].

New Paragraph [0055G] explains that "FIG. 22G graphs the same data as FIG. 22C, showing fold increase for individual subjects." Support for this amendment can be found, for example, in the Specification in Paragraph [0152].

New Paragraph [0055H] explains that "FIG. 22H graphs the same data as FIG. 22D, showing fold increase for individual subjects." Support for this amendment can be found, for example, in the Specification in Paragraph [0152].

In addition, the Specification has been amended such that the SEQ ID NOs contained in the Specification correspond to the SEQ ID NOs provided in the Sequence Listing.

Claim Objections

Claims 73, 91, and 215 have been amended to address the Examiner's objections. All claim informalities identified by the Examiner have been corrected. Thus Applicant requests that the Examiner withdraw the objections.

Claim Rejections under 35 U.S.C. § 112

Claims 93, 238, and 239 have been canceled, thereby rendering the rejection of these claims moot.

Written Description

Claim 73 has been rejected under 35 U.S.C. § 112, ¶ 1 as failing to comply with the written description requirement. The Examiner suggests that the Specification fails to define or provide any disclosure to support the claim limitation "spiked control RNA is non-homologous to

RNA from the [whole] blood." Applicant respectfully disagrees. Paragraph [0078] of the Specification provides that "[i]n particularly preferred embodiments where the sample being tested is human blood, the control RNA is not homologous to RNA present in human blood." Thus Applicant contends that Claim 73 satisfies the written description requirement in its present form.

Claim 233 has been rejected under 35 U.S.C. § 112, ¶ 1 as failing to comply with the written description requirement. This claim has been amended to address the Examiner's objections. Support for the amendment can be found in the Specification in Table 1. Thus Applicant contends that Claim 233 satisfies the written description requirement in its current form.

Claim 217 has been rejected under 35 U.S.C. § 112, ¶ 1 as failing to comply with the written description requirement. The Examiner suggests that the Specification fails to disclose that "a plurality of different antisense primers for different [target] mRNAs are present in the lysis buffer." Applicant respectfully disagrees. As discussed in the Office Action response submitted November 26, 2008, Paragraph [0080] of the Specification explains that "by adding multiple antisense primers for different targets, each gene can be amplified from the aliquot of cDNA." One of ordinary skill in the art would understand that the "plurality of different antisense primers for different target mRNAs" correspond to the "multiple antisense primers for different targets" described in Paragraph [0080]. Thus Applicant contends that Claim 217 satisfies the written description requirement in its present form.

As discussed above, Applicant contends that pending Claims 73, 233, and 217 have sufficient written description support in present form.

Indefiniteness

Claims 73, 75, 77-88, 91-93, 215, 217-219, 231-233, 238, and 239 have been rejected under 35 U.S.C. § 112, ¶ 2 as indefinite. With reference to the paragraph numbers used by the Examiner, the following amendments and arguments address the Examiner's rejections:

9. The phrase "the sample mRNA" in step (f) of Claim 73 has been replaced with "the target mRNA."
10. The term "mRNA" in step (h) of Claim 73 has been replaced with "target mRNA."
11. Claim 77 has been amended to clarify that the anticoagulant is heparin.

12. Claim 78 has been amended to clarify that the term "filtration" was intended to refer to step (c) of Claim 73.

13. Claims 80 and 81 have been amended to clarify that the spiked control RNA is applied to each well of the multi-well filter plate. Support for these amendments can be found, for example, in Paragraph [0078] of the Specification.

14. Claim 83 has been amended to depend on Claim 73 and parallel the language of Claim 75. Support for this amendment can be found, for example, in Paragraph [0013] of the Specification.

15. Applicant contends that Claim 88 is not indefinite in present form. Paragraph [0011] of the Specification explains that "[t]he transfer of lysate to the oligo(dT)-immobilized plate can be accomplished using centrifugation, vacuum aspiration, positive pressure, or washing with ethanol followed by vacuum aspiration." In addition, Examples 1-3 and 5-7 in the Specification discuss the transfer of lysate using centrifugation.

16. Claim 91 has been amended to clarify that the term "mRNA" recited in this claim refers to "target mRNA."

17. The phrase "specific mRNA" in Claim 91 has been replaced with "target mRNA."

18. Claim 92 has been amended to clarify that the specific antisense primers are applied to each well of the multi-well filter plate. Support for this amendment can be found, for example, in Paragraphs [0081] and [0125] of the Specification. Claim 93 has been canceled.

19. Claim 215 has been amended to clarify that the target mRNA is quantified by quantifying the cDNA in solution.

20. Claim 215 has been amended to clarify that "primers" recited in line 2 of step (g) refers to "further antisense primers" and that the limitation "without heat denaturation" means "without heat denaturation of said target mRNA and said cDNA formed by extension of the antisense primers."

21. The term "cDNA" in Claim 218 can refer to "cDNA formed by extension of the antisense primers" or to "cDNA formed by extension of the immobilized

oligo(dT)." Thus Claim 218 has been amended and new Claim 240 has been added.

22. Claim 231 has been amended to clarify that the target mRNA is mRNA of apoptosis genes involved in leukemia. Support for this amendment can be found, for example, in Table 1 of the Specification.
23. See paragraph 22 above.
24. Claim 232 has been amended to clarify that the target mRNA is mRNA of cytokines. Support for this amendment can be found, for example, in Table 1 of the Specification.
25. See paragraph 24 above.
26. Claim 233 has been amended to clarify that the target mRNA is mRNA responsible for apoptosis development. Support for this amendment can be found, for example, in Table 1 of the Specification.
27. Claim 238 has been canceled.
28. Claim 239 has been canceled.

Thus, Claims 73, 75, 77-88, 91-92, 215, 217-219, and 231-233 should now be in condition for allowance.

No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, Applicant is not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. Applicant reserves the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child, or related prosecution history shall not reasonably infer that Applicant has made any disclaimers or disavowals of any subject matter supported by the present application.

Co-Pending Applications of Assignee

Applicant wishes to draw the Examiner's attention to the following co-pending applications of the present application's assignee.

Docket No.	Serial No.	Title	Filed
HITACHI.55CP2D 3	11/803,663	DEVICE AND METHOD FOR HIGH-THROUGHPUT QUANTIFICATION OF MRNA FROM WHOLE BLOOD	May 15, 2007
HITACHI.55CP2D 2	11/803,594	DEVICE AND METHOD FOR HIGH-THROUGHPUT QUANTIFICATION OF MRNA FROM WHOLE BLOOD	May 15, 2007
HITACHI.55CP2D 1	11/803,593	DEVICE AND METHOD FOR HIGH-THROUGHPUT QUANTIFICATION OF MRNA FROM WHOLE BLOOD	May 15, 2007
HITACHI.55CP2C1	11/525,515	DEVICE AND METHOD FOR HIGH-THROUGHPUT QUANTIFICATION OF MRNA FROM WHOLE BLOOD	September 22, 2006
HITACHI.55CP2C2	11/376,018	DEVICE AND METHOD FOR HIGH-THROUGHPUT QUANTIFICATION OF MRNA FROM WHOLE BLOOD	March 15, 2006

Applicant understands that the Examiner has access to sophisticated databases available within the USPTO that will allow full access to the file histories of these applications. As such, Applicant respectfully requests that the Examiner review these file histories for any actions that may be relevant to the prosecution of the present application.

CONCLUSION

In view of the foregoing, the present application is believed to be fully in condition for allowance. However, should any remaining impediments to allowance be identified by the Examiner, the Examiner is respectfully invited to contact the undersigned attorney at the telephone number appearing below.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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